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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: S. Jayaraman

Application No.: 09/924,540

Filed: August 9, 2001

Examiner: L. Channavajjala

Attorney Docket No: 795-A03-012

Group Art Unit: 1615

Confirmation No. 1989

For: COATED FILTER BAG MATERIAL FOR ORAL ADMINISTRATION OF MEDICAMENT IN LIQUID AND METHODS OF MAKING SAME

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant hereby respectfully submits his brief in support of his appeal to the Board of Patent Appeals and Interferences from the decision dated April 27, 2005 of the Examiner final rejection of claims 3-19, 26, 31-35, 37 and 38 of the above-referenced application.

CERTIFICATE OF EXPRESS MAIL

I hereby certify under 37 CFR §1.10 that the attached paper(s) or fee(s) is/are being deposited with the United States Postal Services "Express Mail Post Office to Addressee" to Mail Stop Appeal Brief COMMISSIONER FOR PATENTS, P.O. BOX 1450 ALEXANDRIA, VA 22313 On September 27, 2005

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1. REAL PARTY IN INTEREST

Appellant is the real party in interest.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

3. STATUS OF CLAIMS

Claims 1, 2, 20-25, 27-30, and 36 have been cancelled and claims 3-19, 26, 31-35, 37 and 38 are pending. Claims 3-19, 26, 31-35, 37 and 38 were finally rejected in the Office Action dated April 27, 2005, and are on appeal.

Attached hereto is an Appendix containing a copy of claims 3-19, 26, 31-35, 37 and 38, which are the claims involved in this appeal.

4. STATUS OF AMENDMENTS

Appellant filed an Amendment After Final on June 27, 2005, the Amendment After Final was acted upon but denied entry by the Examiner as provided in the Advisory Action Before the Filing of an Appeal Brief dated June 18, 2005.

5. SUMMARY OF THE INVENTION

The history of medical science is replete with developments in techniques and devices for delivering medicinal agents to patients. One commonly known example is oral medications, such as medicines prepared in a capsule or tablet form. But many people have trouble swallowing oral medications. Past solutions to this problem have included devices that allowed medicinal agents to be loaded into a straw or tube so that the dosage could be delivered to the patient as they drink a beverage. Two examples of such devices are described in U.S. Patent Nos. 5,718,681 and 5,921,955, both of which were discussed in the specification of this application. One drawback to the devices, however, is that they may be inconvenient to use and require complex loading of the medicinal agent into the straw. Likewise, powdered preparations are commercially available for dissolving an active ingredient in water, yet they have met with

limited commercial success, perhaps due to the artificial taste associated with them. Thus, there remains a need for improved devices that can deliver medicinal agents to people who may be unable or unwilling to use other delivery methods (such as tablets or syringes) or who may be interested in receiving medicinal agents in a more convenient manner.

The present invention is directed to a more convenient drug delivery device. In particular, the invention relates to a filter bag used for hot or cold drinks made with porous material that has or is coated with a medicinal agent. A beverage concentrate (e.g., tea leaves, powdered milk, soup, cocoa, or juice, etc.) is disposed inside the bag and is separate from the medicinal agent in the porous material. When used, the bag is placed in a liquid, thereby allowing the beverage concentrate and a therapeutically effective amount of medicinal agent to be released into the liquid.

Although not required in every instance of the invention, in some cases the medicinal agent solubilizes when in contact with the liquid so that it may be dispersed into the liquid to provide a predetermined dosage amount. While the claims require that the medicinal agent released in the liquid provides a therapeutic response upon oral administration, there is no requirement that the medicinal agent fully dissolves into the liquid instead of being released, for example, as a suspension, as a mixture, or in some other form.

The medicinal agent in the porous material of the filter bag may include a pharmaceutical active, a supplemental nutrient, or a beneficial agent. As will be shown in detail below, each of these terms are repeatedly discussed and described throughout the specification. One example of a medicinal agent that may be used with a filter bag of the presently claimed invention is aspirin. As will be discussed below, this is the only claimed embodiment that the Examiner found in compliance with the written description and enablement requirements of 35 U.S.C. §112.

The application and pending claims also describe at length several ways to construct the filter bag. For instance, the medicinal agent may be disposed between two layers of porous material. In another claimed embodiment, a medicinal agent is disposed between the porous material and a drug releasing element such as gelatin that can gradually dissolve and allow the medicinal agent to be released into the liquid. In addition, the filter bag may utilize enzymatic or temperature-dependent agents to control the rate of release of the medicinal agent into the liquid.

Other claimed embodiments of the invention are directed to the use of preservatives to increase product shelf life and to the use of additives to enhance flavor. Finally, the application and pending claims also provide specific details about the type of materials that may be used to form the porous layer of material.

6. ISSUES

A. Whether claims 3-19, 26, 31-35 and 37 comply with the written description requirement under 35 U.S.C. §112, first paragraph.

B. Whether claims 3-19, 26, 31-35 and 37 are enabling for a filter bag coated with a pharmaceutical, beneficial agent or a supplemental nutrient under 35 U.S.C. §112, first paragraph.

C. If any rejections under 35 U.S.C. §§102 and 103 from the May 19, 2004 Non-Final Office Action still apply, whether claims 3-19, 26, 31-35 and 37-38 are patentable over any combination of the references relied upon by the examiner, namely GB 1603414, JP 09108111, CN 1104036, JP 53075346.

7. GROUPING OF CLAIMS

A. Rejections Based on Written Description and Enablement

For purposes of the Examiner's written description and enablement rejections, the claims may be grouped as follows:

Group I: Claims 6-19 and 37 stand or fall together.

Group II: Claims 26 and 31-35 stand or fall together.

Group III: Claim 3 stands or falls by itself.

Group IV: Claim 4 stands or falls by itself.

Group V: Claim 5 stands or falls by itself.

The claim groups Appellant has provided are believed to be separately patentable for purposes of the written description and enablement rejections.

Appellant selected these claim groups because they correspond to different levels of description and specificity regarding the disputed issue of the medicinal agent. Group I includes independent claim 37 and dependent claims reciting additional features or elements that the Examiner has not indicated, and therefore are not believed to be, in dispute for purposes of written description and enablement. Similarly, claims in Group II include independent claim 26 as well as dependent claims the Examiner has not indicated are at issue for purposes of written description or enablement.

The remaining groups have claims that recite features that further clarify the medicinal agent, which claim 37 recites may be a pharmaceutical active, a supplemental nutrient, a beneficial agent, or combinations thereof. Group III has claim 3, which specifies drugs or agents that further define the term "pharmaceutical active". Group IV has claim 4, which further clarifies the term "supplemental nutrient". Group V has claim 5, which provides greater specificity regarding the term "beneficial agent". As discussed below, additional features and further details regarding these claim terms can be found throughout the specification.

Claim 38, which identifies the pharmaceutical active as being aspirin, has not been included in any grouping for this issue because the Examiner has agreed this claim meets the requirements for enablement and written description. The Examiner did not provide an explanation in her April 27, 2005 Final Office Action, however, for her rejection of claim 38. Appellant respectfully submits that this appeal is for any pending ground for rejecting any pending claims in this case.

B. Rejections Based on 35 U.S.C. §§102 and 103

For purposes of the Examiner's rejections based on references cited during prosecution, none of the claims stand or fall together. The reasons why Appellant believes the claims are separately patentable for purposes of any pending rejections based on references cited by the examiner are as follows:

Independent claim 26 is different from claim 37 because it recites that the filter bag has two compartments disposed in side by side relation to one another. The Examiner has not indicated anything that discloses or suggests this feature.

The claims that depend from independent claim 37 each also recite features that merit separate consideration. As indicated above, dependent claims 3, 4 and 5 further clarify the terms "pharmaceutical active", "supplemental nutrient", and "beneficial agent", respectively. The reasons for considering these claims separately have already been articulated above for the first issue under appeal, and therefore are not repeated here.

Claim 6 indicates that the filter bag may be configured for use in either hot or cold drinks, while in some of her rejections for the first issue on appeal the Examiner appears to be incorrectly assuming a requirement that the bag only be used in hot beverages. Similarly, claim 7 recites that the agent may be adapted to solubilize when in contact with a liquid, which the Examiner appears to have imposed as a requirement of all the claims in her 112 rejection. Claim 8 further recites that the agent may release a predetermined dosage amount into the liquid.

Claim 9 indicates that the medicinal agent is disposed between two layers of porous material. The Examiner has not cited any reference that discloses or suggests this additional structure. Claims 10-13 introduce related but distinct features regarding the presence of drug releasing element. In particular, claim 10 recites that the medicinal agent may be in a mixture with a drug releasing element, while claim 11 states that the drug releasing agent may be a separate coating or layer. Claim 12 indicates that the drug releasing agent may be gelatin, while claim 13 recites that the gelatin dissolves to release the medicinal agent.

Claims 14-17 are directed to different agents that may be present for different purposes. For example, claim 14 (and claim 31, which depends from claim 26) recites the presence of an enzymatically active material, while claim 15 (and also claim 32) recites that the medicinal agent is in a mixture with a temperature releasing agent. Likewise, claim 16 recites that the medicinal agent is in a mixture with a material that prolongs shelf life, while claim 17 (and claim 33) recites that a flavor enhancer is present with the medicinal agent. Each of these features is separate and distinct from the other claims, and therefore merits separate consideration on appeal.

Claims 18 and 19 are once again different from the other claims. Here, claim 18 (and claim 34) provides greater definition for the porous material, and claim 19 provides more specificity regarding the beverage concentrate disposed inside the bag.

As indicated above, claims 31-35 recite similar features as found in other claims, but should be considered separately because of the distinct differences between the independent claims. Finally, claim 38 recites that the pharmaceutical active is aspirin, which once again is different from the features recited in the other claims.

8. ARGUMENT

As previously discussed, this application is directed to an improved way to deliver a medicinal agent with a filter bag made of porous material and having a beverage concentrate disposed inside.

Prosecution of this case has involved a 3-way restriction of the 25 claims initially presented (thereby removing 5 claims from consideration), followed by two office actions representative of a typical course of examination on the merits. In these two office actions, the Examiner imposed substantive rejections based on cited references.

When the Examiner did not reply to an amendment filed after receipt of the November 17, 2003 Final Office Action, Appellant filed a Request for Continued Examination. In the third Office Action for this case, the Examiner proposed new grounds for rejecting the claims based on cited references, but also for the first time rejected the claims on the grounds that they did not meet the written description and enablement requirements of 35 U.S.C. §112. In essence, the Examiner doubted that the specification and claims sufficiently indicated to a skilled artisan that the Appellant was in possession of the invention or described how the invention worked even though by that time she had been conducting examination and issuing office actions in this case for nearly three years.

Appellant once again responded to the Examiner by explaining why the cited references did not render the claims either anticipated or obvious. In addition, appellant contested the Examiner's remarks regarding written description and enablement.

In response, the Examiner made no further remarks regarding her rejection of the claims based on cited references. As a result, it is not clear to Appellant whether the Examiner agrees that these rejections have been overcome or where the Examiner may disagree with Appellant's

arguments. Out of an abundance of caution, Appellant has included any pending substantive rejection in the scope of this appeal.

Instead, the Examiner elaborated further on her reasoning behind making her written description and enablement rejections final. Before filing this appeal brief, appellants attempted to amend the claims to streamline the issues in dispute in this case. In response, the Examiner declined to enter the amendment on the ground that it would require further consideration and possibly a new search.

For the reasons provided below, Appellant respectfully submits that the Examiner's rejections based on 35 U.S.C. §112 reflect an attempt to impose a higher level of specificity from the Appellant than required by law or needed by a skilled artisan to satisfy the written description and enablement standards.

Before discussing the reasons why the 112 final rejections should be removed for grouping of claims, the following is a listing where support for each claim may be found in the specification as found in Patent Application Publication 2003/0032945 A1. Appellant has also indicated where pending claims are supported from originally filed claims:

Claims	Examples of Support in the Specification
3	Paragraphs 10 and 33; original claim 3
4	Paragraphs 11 and 34; original claim 4
5	Paragraphs 12 and 35; original claim 5
6	Paragraphs 1 and 13; original claim 6
7	Paragraph 14; original claim 7
8	Paragraph 30; original claim 8
9	Paragraphs 14 and 36; original claim 9
10	Paragraphs 14 and 19; original claim 10
11	Paragraphs 14 and 38-39; original claim 11
12	Paragraphs 14 and 38-39; original claim 12
13	Paragraphs 14 and 38-39; original claim 13
14	Paragraphs 15 and 40; original claim 14
15	Paragraphs 15 and 40; original claim 15
16	Paragraph 15; original claim 16

Claims	Examples of Support in the Specification
17	Paragraphs 15 and 41-43; original claim 17
18	Paragraphs 16 and 46; original claim 18
19	Paragraph 17; original claim 19
26	Figures 1-3; paragraphs 8-9, 20, 32 and 37
31	Paragraphs 15 and 40; original claim 14
32	Paragraphs 15 and 40; original claim 15
33	Paragraphs 23 and 41-43
34	Paragraphs 16 and 46; original claim 18
35	Paragraphs 23, 30 and 47-48; original claim 25
37	Figure 1; paragraphs 8-9, 20, and 32; original claims 1-2
38	Paragraph 33

Based on the foregoing, the specification amply supports the pending claims.

The Claims Satisfy the Written Description and Enablement Requirements of 35 U.S.C. §112

Claims 3-19, 26, 31-35, and 37 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. With respect to the written description rejection, the Examiner seems to be making two arguments: First, the Examiner appears to believe that the specification fails to describe sufficient details of how medicinal agents "are incorporated in the membrane of the filter bag." Second, the Examiner appears to believe the specification lacks enough detail "as to amounts of medicinal agents incorporated into the filter bag." Notably, neither of these examples corresponds to a recited claim element, but more importantly, they lack merit because they would be relatively simple for a skilled artisan. As explained below, Appellant respectfully disagrees and submits that the subject matter of claims 3-19, 26, 31-35, and 37 is fully supported by the specification.

At the outset, Appellant notes that the level of skill in this field of study is extremely high. Skilled artisans in the relevant field, which in this case may include medical researchers with one or more advanced degrees, several years of experience in drug development and research, and perhaps

assistants and other resources normally available in the research and development of drug delivery devices, would understand from the disclosure in this application that the Appellant was in possession of the invention.

Simply put, the issues raised by the examiner to challenge the claims – namely that Appellant did not specify a range of drug dosages or did not provide a more thorough list of exemplary compounds corresponding to the claim terms – ignores the fact that these issues would be readily understood by skilled artisans.

Compliance with the written description and enablement standards does not require an applicant to provide information that would be potentially trivial to a person of ordinary skill in the art or possibly require routine research. Appellant respectfully submits that doctors, medical researchers, and other persons of ordinary skill in the field having the benefit of this disclosure would not only recognize that appellant had possession of the invention, but also would understand how to use the disclosure with a wide range of medicinal agents.

Two illustrations of this point are U.S. Patent Nos. 5,718,681 and 5,921,955, which were discussed above and disclosed in the background of the invention. When compared to the details provided in the instant application, neither the '681 nor '955 patent provided greater specificity about dosage amounts, the types of medicinal agents that may be used with the devices, or examples having the level of specificity the present Examiner is asking of the Appellant. Appellant respectfully submits that, as is the case here, the reason the '681 and '955 patents do not include detailed descriptions of dosage ranges and the like is because these details were understood or could be determined through routine research by skilled artisans in the 1990s when these patents were filed just as they are well-understood or identifiable today.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.

In this case, all of the claim elements that appear to be the basis for the written description rejection were present in the original claims and in several paragraphs of the specification. Thus, there is a strong presumption that an adequate written description of the invention as embodied in this element is present in the specification as filed. The presumption is even more applicable here where examination proceeded for several years and multiple Office Actions prior to the written description and enablement rejections being first raised.

More importantly, and contrary to the Examiner's assertions, Appellant has described how the medicinal agents "are incorporated in the membrane of the filter bag" and the "amounts of medicinal agents incorporated into the filter bag."

With respect to the Examiner's remarks regarding the amount of medicinal agent to use, the claims, as originally filed and as currently pending recite "a therapeutic effective amount of at least one medicinal agent." This phrase is used throughout the specification and is defined in the specification as "an amount that produces the desired therapeutic response upon oral administration, and can be readily determined by one of ordinary skill in the art. In determining such amounts, the particular medicament being administered, the bioavailability characteristics of the medicament, the dose regime, the age and weight of the intended recipient, and other factors should be considered."

Appellant respectfully submits that it is not necessary to provide an absolute amount of a given medicinal agent in order to satisfy the written description requirement. Patent applications are not required to be cookbooks reciting every step, measurement, or aspect of an invention. In this case, such information is known or readily available to those of ordinary skill in the art. In addition, similar claim language also may be found in the claims of the '681 and '955 patents.[1]

With respect to the Examiner's remarks regarding how the medicinal agents are incorporated with the porous material of the filter bag, the specification does provide methods for incorporating the medicinal agent into the porous material. As illustrated in FIG. 2, the medicament 10 may be sandwiched in between a lower filter bag material layer 30 and an upper filter bag material layer 40. (Page 7, lns. 10-11). In one embodiment, a drug releasing element, such as gelatin, may be impregnated on the surface of the filter bag material after applying the

1 If needed, many other examples of patent claims reciting a "therapeutic amount" of a medicinal agent can be provided to further illustrate the acceptability of this terminology in patent claims.

medicament, thus sandwiching the medicament between the gelatin layer and the filter bag material. (Page 7, lns. 24-26). Other agents to control the release of the medicinal agent are described as well. Moreover, the application also provides detailed description about the porous material. All of this information could be used by skilled artisans to determine not only that the Appellant was in possession of the invention, but also to illuminate several meaningful options for controlling release of the medicinal agent.

In light of the foregoing, reconsideration and withdrawal of the written description requirement rejection is respectfully requested.

Appellant also respectfully disagrees with the Examiner's additional remarks regarding enablement of the claims.

As an initial matter, Appellant notes that the Examiner's remarks in the April 27, 2005 Final Office Action indicate agreement that the specification is enabling for a filter bag coated with aspirin or sildenafil citrate. While this acknowledgement is appreciated, it ignores Appellant's arguments set forth in the prior Response with respect to other specific agents. In particular, the specification discloses a number of other specific agents for coating a filter bag, namely; antihistamine drugs such as H_2 blockers; vitamins and minerals such as traces of selenium, chromium, molybdenum, zinc, and copper, electrolytes, gold compounds; oligosaccharides such as fructo-oligosaccharides, pyruvate precursors in the form of pyruvamide, or pyruvyl-amino acids, such as, pyruvyl-glycine, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, pyruvyl-sarcosamine and their amides. (Page 6, lns.14-24). In short, Appellant respectfully submits there is no basis for finding the specification enabling only for two of the numerous specific examples of medicinal agents provided in the specification.

The Examiner made two arguments in support of her enablement rejections. First, the Examiner asserted that the "specification provides no guidance as to how to prepare the medicament such that it is incorporated in the bag material i.e., as a powder or solubilized and applied [as] liquid coating etc." In addition, the Examiner asserted that the "specification fails to provide details of the conditions (such as temperature) of coating or incorporating the desired agents without loosing [sic] the activity of the compounds." Appellant notes once again that the

preparation of medicinal agents in powder or liquid forms is well known to one skilled in the art and that such information could be obtained without undue experimentation.

But in addition, Appellant further notes that the Examiner's reliance on a high level of solubility for all medicinal agents suggests that she is improperly reading specific examples from the specification into the independent claims. Neither claim 26 nor 37 require high solubility of the medicinal agent, and in fact solubility of the agent is only found in dependent claims (e.g., claim 7). Thus, the doctrine of claim differentiation further precludes the claim interpretation the Examiner has adopted for the independent claims. A skilled artisan reading the claims would not necessarily be limited to making the medicinal agent soluble in the liquid. It may be possible, for instance, for the medicinal agent to form a mixture or suspension in the beverage. Since solubility of medicinal agents is well understood by skilled artisans, this would not present a circumstance where undue experimentation would be required.

Second, the Examiner asserted that the Appellant has "not described if all of the materials claimed i.e., drugs or nutrients or other beneficial agents, are soluble upon contact with liquid, or any mechanism as to how the medicaments claimed are released." The specification provides teaching as to release of the medicinal agent. Specifically, the medicament may solubilize when in contact with liquid and is dispersed in the proper dosage amount into the liquid for oral consumption. (Page 5, lns. 29-31). However, this is not a requirement for every embodiment and is not recited in the claims as a limitation. Additionally, upon immersion in a liquid 70, a gelatin layer 40 may break down into gelatin particles 40a, which dissolve into the liquid 70, and the medicament 10 is released into the liquid 70, as depicted in FIG. 4. (Page 7, lns. 29-32). Appellant respectfully submits that it is not necessary to set forth the solubility limits of every medicinal agent in a particular liquid at a given temperature range. Rather, the solubility of these medicinal agents is well known to one skilled in the art such that such information could be obtained without undue experimentation.

Even if a skilled artisan needed reminding that it is desirable that the medicinal agent ultimately be administered to a patient by drinking the beverage, the specification further explains that the medicament is "dispersible in the medium of the liquid for ingesting during an interval just prior to or during feeding, in order to meet the objectives of the invention." Skilled

artisans having the benefit of the disclosure of this application would immediately recognize that this can be achieved in several ways.

In short, a skilled artisan has ample information from the specification and claims to recognize, understand, and carry out the claimed invention.

The Examiner's remarks regarding conditions of the coating are equally without merit. One of ordinary skill would also appreciate, for example, that the temperature should be controlled to avoid inactivation of the medicinal agent. The Examiner seems to believe that the invention is somehow limited to high temperature beverages even though the specification teaches otherwise. *See, e.g.,* paragraphs 1 and 13. Moreover, dependent claim 6 specifically recites that the filter bag may be adapted for use in cold or hot liquids. Thus, the Examiner has either misread the specification or misunderstood the invention in order to impose an artificial conclusion regarding enablement.

In light of the foregoing, Appellant submits that claims 3-19, 26, 31-35 and 37 are enabled by the specification. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 112 rejections.

The Claims Are Patentable Over the References Relied on by the Examiner

The Rejections under 35 U.S.C. §102(b)

In her May 19, 2004 Office Action, the Examiner rejected Claims 6-8, 18, 19, 26, 34, 35 and 37 under 35 U.S.C. 102(b) are being anticipated by GB 1603414 ("GB"). This was the first instance that the Examiner had rejected the claims based on the GB reference. It is unclear, however, whether the Examiner maintained this rejection in her Final Office Action because the Examiner did not substantively discuss any of the merits of this rejection or any of the arguments Appellant presented in its August 19, 2005 Response. For the reasons set forth below, Appellant wishes to preserve the full extent of its right to appeal, and thus out of an abundance of caution submits the following remarks about why the rejected claims are not anticipated by GB.

As noted by the Examiner, GB discloses a method for producing tea bags from which infusions having improved colour can be derived. (Page 1, lns. 31-32). Teas brewed in water with high temporary hardness often have an undesirable grey-brown colour. (Page 1, lns. 12-13). It is known that citric acid improves the colour of the tea liquor obtained on infusion. (Page 1, lns. 16-17).

The improved colour of the tea liquor on infusion is obtained if the tea bag is made from water-pervious sheet material having edible acidic material incorporated therein. (Page 1, lns. 34-36). The acidic material being selected from the following: citric acid, malic acid, glutaric acid, tartaric acid, succinic acid, monosodium hydrosulphate, and buffering mixtures of any of these acidic material with water-soluble salts of the same acidic materials. (Page 1, lns. 45-48).

As such, GB discloses a tea bag having an edible acidic material incorporated thereon for improving the color of the tea infusions for teas brewed in water with high temporary hardness. The only disclosed improvement by the acidic material is an improved color in the tea infusion. The GB patent notes flavor in determining appropriate acidic material, specifically in the table in Examples 1-6 (Page 3, lns. 1-8) and on page 4, lines 7. However, GB does not disclose that the acidic material improves the flavor of the tea infusion. Furthermore, GB does not disclose that the acidic material is a therapeutically effective amount of a medicinal agent which produces a therapeutic response upon oral administration.

In contrast, the present invention is directed to a coated filter bag for oral administration of medicament. The present invention advantageously allows for a palatable, easy method for administering medicaments in proper dosage amounts for those who prefer not to or are not able to swallow a pill. (Page 5, ln. 31 – page 6, ln. 2). The medicament used for coating the filter bag material is present in a therapeutically effective amount and may include pharmaceutical actives, supplemental nutrients, genetically derived material, other beneficial agent, or combinations thereof. (Page 6, lns. 6-8). As used herein, "therapeutically effective amount" is an amount that produces the desired therapeutic response upon oral administration. (Page 6, lns. 9-11).

Claims 26 and 37 now recite a filter bag for oral administration of medicament that includes at least one sheet of porous material forming a sealed bag. The filter bag includes a therapeutically effective amount of at least one medicinal agent incorporated into the porous

material. The therapeutically effective amount of the at least one medicinal agent produces a therapeutic response upon oral administration.

Appellant submits that each and every element of the invention as recited in claims 26 and 37 are not disclosed in GB. As noted above, GB is directed towards a tea bag having an edible acidic material incorporated thereon. The acidic material is disclosed only as improving the color of the tea infusions for teas brewed in water with high temporary hardness. GB does not disclose a medicament applied to the material that makes the tea bag. Specifically, GB does not teach or suggest a therapeutically effective amount of at least one medicinal agent which produces a therapeutic response upon oral administration.

In light of the foregoing, amended independent claims 26 and 37 are respectfully submitted to be patentable over GB. As claims 6-8, 18, 19, and 37 depend from amended claim 37 and claims 34 and 35 depend from amended claim 26 and necessarily include all the elements of their respective base claims, Appellant respectfully submits that these claims are also allowable over the cited reference at least for the same reasons.

The Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 3-5, 9, and 38 under 35 U.S.C. §103(a) as being unpatentable over a combination of JP 09108111 (JP '111) and GB or unpatentable over GB and JP '111 in view of CN 1104036 (CN).

Claims 10-17 and 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over a combination of JP '111 and GB as applied to claims 3-5, 9-11, and 38 above, and further in view of JP 53074346 (JP '346) or unpatentable over GB and JP '111 in view of CN applied to claims 3-5, 9-11, and 38, and in further view of JP '346.

Claims 3-5, 9-17, and 38 depend from independent claim 37 and claims 31-33 depend from independent claim 26. As noted above, claims 26 and 37 are submitted as being patentable over GB. The combinations of JP '111, CN, and/or JP '346 do not remedy the deficiencies of GB. Accordingly, as claims 3-5, 9-17, and 38 depend from claim 37 and claims 31-33 depend from independent claim 26 and necessarily include all the elements of their respective base claim, Appellant respectfully submits that these claims are also allowable over the cited

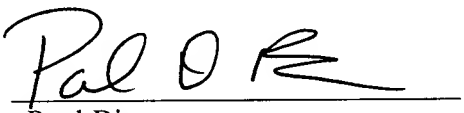
combinations at least for the same reasons. Furthermore, each of the secondary references has been previously discussed in prior Responses to Office Actions.

Nevertheless, Appellant will address the proposed combination of references. With respect to the combination of GB with JP '111 or CN, it appears to be suggested to apply the various beverage concentrates taught by JP '111 and CN on the tea bag of GB. Other than improper hindsight, it is unclear why one of ordinary skill in the art would be motivated to apply a coating of oolong tea, water chestnut, safflower, or any of the other disclosed beverages on a tea bag which contains tealeaves. This could possibility interfere with the color (and to the extent disclosed flavor) improving purpose of GB. Thus, if anything, GB would actually teach against this combination.

In light of the foregoing, it is respectfully submitted that dependent claims 3-5, 9-17, 31-33 and 38 are not taught or suggested by the cited prior art, either alone or in any combination.

Respectfully submitted,

Dated: September 27, 2005

By: 

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9. APPENDIX: LISTING OF CLAIMS INVOLVED IN THIS APPEAL

3. The filter bag of claim 37, wherein the pharmaceutical active is selected from the group consisting of a chemotherapy agent, an anti-neoplastic agent, a mood elevating drug, a depressant drug, an anti-diabetic drug, an anti-ulcer drug, a gastrointestinal drug, an infertility drug, a fertility drug, a hormone, an erectile dysfunction agent, an anti-inflammatory drug, a coagulation drug, an anti-coagulent drug, an anti-platelet agent, an ace inhibitor, a cardiovascular conditioning drug, a cholesterol reducing agent, a lipid reducing agent, an antihistamine drug, an anti-infective agent, an autonomic drug, a central nervous system agents, a smooth muscle relaxant, an antitussive agent, a mucolytic agent, and a combination thereof.

4. The filter bag of claim 37, wherein the supplemental nutrient is selected from the group consisting of eucalyptus, glutamine, arginine, a fermentable dietary fiber, a non-fermentable dietary fiber, a phytochemical, an anti-oxidant, a mineral, an amino acid, an oligosaccharide, a short chain fatty acid, a pyruvate precursor, a pyruvyl-amino acid, d-chiroinositol, lactoferrin, a marine oil, an ascorbic acid, and a combination thereof.

5. The filter bag of claim 37, wherein the beneficial agent is selected from the group consisting of a probiotic, an enzyme, an electrolytic agent, a caloric agent, a water balance agent, a rehydration solution, a diagnostic agent, a vitamin, and a combination thereof.

6. The filter bag of claim 37, wherein the filter bag is adapted for use in cold or hot liquids.

7. The filter bag of claim 37, wherein the agent is adapted to solubilize when in contact with a liquid.

8. The filter bag of claim 7, wherein the agent is adapted to be dispersable in a predetermined dosage amount into the liquid.

9. The filter bag of claim 37, wherein the at least one medicinal agent is disposed between two layers of the at least one sheet of porous material.

10. The filter bag of claim 37, wherein the at least one medicinal agent is present in a mixture with a drug releasing element and the mixture is applied to the at least one sheet of porous material.

11. The filter bag of claim 37, wherein the at least one medicinal agent is disposed between the at least one sheet of porous material and a layer comprising a drug releasing element.

12. The filter bag of claim 11, wherein the drug releasing element is gelatin.

13. The filter bag of claim 12, wherein the gelatin is dissolvable when in contact with the liquid to release the at least one medicinal agent into the liquid.

14. The filter bag of claim 37, wherein the at least one medicinal agent is mixed with at least one enzymatically active material.

15. The filter bag of claim 37, wherein the at least one medicinal agent is present in a mixture comprising a temperature releasing agent.

16. The filter bag of claim 37, wherein the at least one medicinal agent is present in a mixture comprising a degradable material adapted to provide a prolonged shelf life for the medicament.

17. The filter bag of claim 37, wherein the at least one medicinal agent is present in a mixture comprising a flavor producing or reducing agent.

18. The filter bag of claim 37, wherein the at least one sheet of porous material is selected from the group consisting of reinforced paper, knitted material, woven material, fibrous material, and a combination thereof.

19. The filter bag of claim 37, wherein the filter bag holds a beverage concentrate selected from the group consisting of tea leaves, powdered tea, powdered milk, apple cider, powdered soup, hot cocoa, and instant coffee.

26. A filter bag for oral administration of medicament comprising:

at least one sheet of porous material forming a sealed bag comprising first and second compartments disposed in side by side relation to one another;

a beverage concentrate disposed in one of the compartments; and

a therapeutically effective amount of at least one medicinal agent incorporated into the porous material, wherein the therapeutically effective amount of the at least one medicinal agent produces a therapeutic response upon oral administration,

wherein the medicinal agent differs in composition from the beverage concentrate and the medicinal agent and the beverage concentrate are not directly mixed.

31. The filter bag of claim 26, further comprising at least one enzymatically active material.

32. The filter bag of claim 26, further comprising a temperature releasing agent.

33. The filter bag of claim 26, further comprising a flavor producing or reducing agent.

34. The filter bag of claim 26, wherein the at least one sheet of porous material is selected from the group consisting of reinforced paper, knitted material, woven material, fibrous material, and a combination thereof.

35. The filter bag of claim 26, wherein the beverage concentrate comprises tea concentrate.

37. A filter bag for oral administration of medicament comprising:

at least one sheet of porous material having a therapeutically effective amount of at least one medicinal agent incorporated therein, the at least one sheet of porous material forming a sealed bag having a beverage concentrate therein separate from the medical agent;

wherein the therapeutically effective amount of the at least one medicinal agent produces a therapeutic response upon oral administration,

wherein the at least one medicinal agent is selected from the group consisting of a pharmaceutical active, a supplemental nutrient, a beneficial agent, and a combination thereof, and

wherein the medicinal agent is incorporated into the at least one sheet of porous material without directly mixing with the beverage concentrate.

38. The filter bag of claim 37 wherein the pharmaceutical active is aspirin.